



*American Academy of Dermatology Association*

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Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852  
Docket No: 2005N-0394

To Whom It May Concern:

On behalf of more than 14,000 members of the American Academy of Dermatology Association, I submit the following comments with respect to the ongoing development of a risk communication strategy for the Center for Drug Evaluation and Research (CDER). These comments are in response to the public hearing held on December 7 and 8, 2005.

The Academy believes strongly in communicating accurate and reliable safety information to patients; however, we believe that this information is most effectively communicated by the patient's physician. Although CDER should continue to include drug safety information on its website, we would encourage CDER to develop a risk communication strategy that focuses on the doctor/patient relationship and to use that relationship to more effectively communicate safety issues. Supplying patients with information by which they have no perspective to process it only adds confusion and fear to the situation. A physician can present the information in a comprehensive health care plan for each individual.

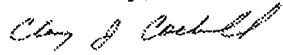
Understanding the complexities of ensuring that every physician has access to this information, the Academy would like to work with CDER in developing an appropriate and effective system. The majority of America's physicians belong to the Alliance of Specialty Medicine, or to an individual specialty medical society, like the Academy. We encourage CDER to use pre-existing relationships with the Alliance and these individual specialty associations to relay accurate and timely information to physicians. Additionally, most physicians and their staff access electronic mail on a regular basis. Having CDER immediately notify physicians and their staff of drug safety issues through e-mail would be a timely and inexpensive method. Physicians could be encouraged to sign-up for e-mail alerts on the CDER website, and medical societies could play a role in this process as well. Again, the Academy would very much like to work with CDER on how to better communicate drug safety information to physicians and patients, the people who need it most.

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Thank you for the opportunity to submit these comments. Should you need any further information or should you like to discuss these comments further, please contact Vera LeBrun at 202-842-3555 or [vlebrun@aad.org](mailto:vlebrun@aad.org).

Sincerely,



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President

CJC/vel

cc: Stephen P. Stone, M.D., President-Elect  
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